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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,819	03/18/2004	Rae Ellen Syverson	KCC 4749.1 (K-C 16,858.1)	7018
45736	7590	01/14/2008	EXAMINER	
Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP ONE METROPOLITAN SQUARE SUITE 2600 ST. LOUIS, MO 63102			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1611	
			NOTIFICATION DATE	DELIVERY MODE
			01/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary	Application No. 10/803,819	Applicant(s) SYVERSON ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 5, 12, 13 and 26-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11 and 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11-16-07 & 12-13-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of IDS dated 11-16-07 and 12-13-07; and response dated 10-22-07 is acknowledged.

Claims 1-60 are pending. Claims 5, 12, 13 and 26-60 have been withdrawn as non-elected. Claims 1-4, 6-11 and 14-25 have been examined.

Response to Arguments

Applicant's arguments filed 10-22-07 have been fully considered but they are not persuasive.

1. Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al. (J. Clin. Microbiol. 1987) and Lambert (J Applied Microbiol.) in view of US 6,416,779 to D' Augustine et al OR D'Augustine et al in view of Robbins et al and Lambert.

The complete text of the rejection may be found in the previous action, which is incorporated herewith.

RESPONSE: Applicants' detailed arguments, not reproduced here, have been considered but not found persuasive. It is argued that Robbins and Lambert do not teach the use of phenoxyethanol (or any compound having the structure of the first active ingredient as required in claim i) on a non-absorbent substrate for insertion into the vagina for inhibiting exoproteins from Gram positive bacteria and that nowhere in Robbins et al. or Lambert is a non-absorbent substrate being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a

tampon applicator, and a douche even mentioned. It is argued that in an attempt to find each and every element of claim 1 as required by the M.P.E.P. for a determination of prima facie obviousness, the Office cites the D'Augustine et al. reference for combination with Robbins et al. and Lambert.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)..

Applicants argue that the office failed to provide a suggestion or motivation, either in references themselves or in the knowledge generally available to one of an ordinary skill in the art to combine the references and that the references actually teach away from the combination. Applicants arguments are not persuasive because a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). In the instant case, the teaching of Lambert that phenethyl alcohol is superior to phenoxyethanol does not lead to the conclusion that the latter is not effective in inhibiting *S. aureus*. Further, the prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable

expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, one of an ordinary skill in the art would have been motivated to include phenoxyethanol of Lambert on the non-absorbent articles of D'Augustine with a reasonable expectation that phenoxyethanol is effective in inhibiting the exoprotein produced by *S. aureus* because Robbins admittedly teaches tampons support vaginal infections such as those caused by *S. aureus* by supplying a fibrous surface and that inhibitors such as a surfactant may inhibit exoprotein production. It would have been reasonable for one of an ordinary skill in the art to expect that *S. aureus* exoprotein production can be inhibited by any inhibitor exhibits such activity. With respect to the argument regarding KSR Int'l Co. v. Teleflex, inc., and the unpredictability of exoprotein inhibitors, one of an ordinary skill in the art would have predictably combined the teachings of Lambert, Robbins and D' Augustine because of the teachings of Robbins regarding the importance of including exoprotein inhibitors on tampons so as to reduce toxic shock syndrome caused by *S. aureus* and the effect of phenoxyethanol has been established by Lambert ruling out any unpredictability.

2. Claims 1-4, 6-11 and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al. (J. Clin. Microbiol. 1987) and Lambert (J Applied Microbiol.) in view of Syverson (U.S. 5,612,045) or Syverson in view of Robbins et al. and Lambert.

Applicants' arguments regarding Robbins et al. and Lambert have been addressed above. It is argued that Syverson reference does not overcome this

deficiency as Syverson is merely directed to absorbent articles, such as catamenial tampons, which include an effective amount of an ether compound to substantially inhibit the production of exotoxins by Gram positive bacteria. Significantly, nowhere in Syverson is a first active ingredient as set forth in claim 1 even mentioned, much less that such a compound has antimicrobial properties or is effective in inhibiting the production of exoprotein from Gram positive bacteria when deposited on a non-absorbent substrate selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. As none of the cited references teach or suggest using the first active ingredient having the structure as set forth in claim 1 on a non-absorbent substrate, selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche, for insertion into the vagina for inhibiting exoproteins from Gram positive bacteria, claim 1 is patentable over the combination of Robbins et al., Lambert, and Syverson. Applicants' arguments are not persuasive because Syverson teaches both absorbent and non-absorbent articles with *S. aureus* exoprotein inhibiting compounds. Thus, one of an ordinary skill in the art would have been motivated to include phenoxyethanol of Lambert on the non-absorbent articles of Syverson with a reasonable expectation that phenoxyethanol is effective in inhibiting the exoprotein produced by *S. aureus* because Robbins admittedly teaches tampons support vaginal infections such as those caused by *S. aureus* by supplying a fibrous surface and that inhibitors such as a surfactant may inhibit exoprotein production. It

would have been reasonable for one of an ordinary skill in the art to expect that S.aureus exoprotein production can be inhibited by any inhibitor exhibits such activity.

DOUBLE PATENTING rejection of record has been maintained because applicants' stated that the rejection is provisional and agreed to address the merits of the rejection if the listed application matures in to a patent before the instant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615

January 6, 2008



LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER